35. A method of treating depression in a mammal which comprises the oral administration of a therapeutically effective amount of a composition or tablet of claim 1, 2, 13, 14, 21, 23, 24, 30, 33 or 34 to said mammal.

REMARKS

Claims 1-37 are pending in this application for the Examiner's review and consideration. Claim 38 has been canceled and its subject matter incorporated into claim 30, and claims 13 and 14 have been amended to recite preferred embodiments of the invention. These amendments are made without prejudice to Applicants' right to pursue the subject matter recited by any of the canceled or amended claims in one or more continuation, divisional, or continuation-in-part applications. Claims 17-20, 22, 29, and 35 have been amended to correct formal defects. A marked-up version of the amendments is provided in Appendix A, attached hereto; the pending claims are provided in Appendix B, attached hereto.

The Rejections Under 35 U.S.C. §112 Should be Withdrawn

On page 2 the of the Office Action, claim 22 is rejected for lacking an antecedent basis. This rejection is obviated by the amendment provided herein.

On page 7 of the Office Action, claims 13-20, 22, 29, 30-32, 35, 37, and 38 are rejected under the second paragraph of §112, allegedly "because it is not clear whether the conditions required for the DISSOLUTION TEST in the specification at page 18 remain constant or if they may change over time." This rejection is traversed for the following reasons.

The conditions of the DISSOLUTION TEST are clearly defined in the specification. *See* page 18, lines 9-16. Because it is a well-established principle of patent law that the meaning of the claims are to be interpreted in light of the specification, Applicants respectfully submit that the scope of each of the claimed embodiments of the invention is particularly and clearly recited. Manual of Patent Examining Procedure (M.P.E.P.) § 2173.05(a), citing *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989). Applicants therefore respectfully request that the rejection of claims 13-20, 22, 29, 30-32, 35, 37, and 38 be withdrawn.

The Rejection Under 35 U.S.C. 102(b) Should Be Withdrawn

On page 3 of the Office Action, claims 21, 23-25, and 29 are rejected under 35 U.S.C. 102(e) as allegedly anticipated by U.S. Patent No. 5,830,500 to El-Rashidy *et al.* ("El-Rashidy"). Applicants respectfully traverse the rejection for the following reasons.

A prior art reference must disclose all the elements of a claim in order to anticipate the invention recited by that claim. *See* M.P.E.P. § 2131. There must be no difference between the claimed invention and the reference disclosure as viewed by one of ordinary skill in the art. *Scripps Clinic & Research Fdn. v. Genentech*, 927 F.2d 1565, 1576 (Fed. Cir. 1991). Put another way, "[a] claim is anticipated and therefore invalid only when a single prior art reference discloses *each and every limitation of the claim*." *Glaxo Inc. v. Novapharm Ltd.*, 52 F.3d 1043, 1047, *cert. denied*, 116 S. Ct. 516 (1995) (citations omitted) (emphasis added).

In the event a reference does not explicitly teach all elements of a claim, anticipation can only be shown by inherency if, and only if, the cited reference makes it clear that the missing descriptive matter is *necessarily present* in the thing described in the reference and that it would be so recognized by one of ordinary skill in the art. *In re Robertson*, 169 F.3d 743, 49 U.S.P.Q.2d 1949 (Fed. Cir. 1999) (citing *Continental Can Company USA Inc. v. Monsanto Company*, 948 F.2d 1264 (Fed. Cir. 1991)). Consequently, *inherency cannot be established by probabilities or possibilities*: "[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient to support an assertion of inherency." *In re Oelrich*, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981) (quoting *Hansgirg v. Kemmer*, 102 F.2d 212, 414 (C.C.P.A. 1939)). Therefore, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily* flows from the teachings of the applied prior art." M.P.E.P. § 2112, citing *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in the original).

Claim 21 recites a stable, compressed tablet consisting essentially of racemic fluoxetine, an optically pure enantiomer or a pharmaceutically acceptable salt thereof, and microcrystalline cellulose and pre-gelatinized starch. El-Rashidy does not disclose such a tablet. Instead, El-Rashidy alleges the preparation of a tablet that contains fluoxetine hydrochloride, calcium diphosphate dihydrate, a disintegrant, and a lubricant. *See, e.g.*,

El-Rashidy at col. 2, lines 2-4. Furthermore, the only example it provides of such a tablet does not contain pre-gelatinized starch. Table 1, col. 4, lines 20-33. El-Rashidy therefore does not disclose each and every element recited by claim 21. For this reason, Applicants respectfully submit that El-Rashidy does not anticipate claim 21.

Claim 23 recites an anhydrous solid pharmaceutical composition that comprises racemic fluoxetine, an optically pure enantiomer of racemic fluoxetine or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable excipients. El-Rashidy discloses nothing about anhydrous compositions. The reference simply alleges the preparation of tablets using conventional methods, taking no precautions to avoid their absorption of water.

As Applicants pointed out in their last response, and as discussed further below, the alleged use of dry ingredients is insufficient to ensure that the resulting tablet is anhydrous. As those of skill in the art are well aware, this is because many of the ingredients will readily absorb moisture from the air during the various steps (*e.g.*, mixing and compression) used to prepare the tablet. Further, the tablet itself can absorb water from its surroundings. The anhydrous nature of the tablet recited by claim 23 is therefore not necessarily present in the tablets alleged by El-Rashidy. Indeed, this is clear from the fact that preferred tablets of El-Rashidy contain calcium diphosphate *dihydrate*. For this reason, Applicants respectfully submit that El-Rashidy does not anticipate claim 23.

Because claims 21 and 23 are not anticipated by El-Rashidy, dependent claims 24, 25, and 29 also are not anticipated by that reference. Applicants respectfully request that the rejection of claims 21, 23-25, and 29 under § 102 therefore be withdrawn.

The Rejections Under 35 U.S.C. 103 Should Be Withdrawn

On pages 3-6 of the Office Action, claims 1-35 are rejected under 35 U.S.C. 103(a) as allegedly obvious over El-Rashidy in view of the *Physicians Desk Reference*, 919-923 (50th ed.; 1996) ("PDR") and WO 97/31629 ("the '629 application"). Applicants respectfully traverse this rejection for the reasons discussed below.

In order to properly determine a *prima facie* case of obviousness, an Examiner "must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made." M.P.E.P. § 2142. This is important, as "impermissible hindsight must be avoided and the legal conclusion must

be reached on the basis of the facts gleaned from the prior art." *Id.* Three basic criteria must then be met: first, there must be some suggestion or motivation to modify or combine the cited references; second, there must be a reasonable expectation of success; and third, the prior art references must teach or suggest all the claim limitations. *Id.* at § 2143. With regard to the first criterion, it is important to recognize that the "mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." *Id.* at 2143.01 (emphasis in the original) (citing *In re Mills*, 916 F.3d 680 (Fed. Cir. 1990)).

Ten independent claims are currently pending in this application: claims 1, 2, 13, 14, 21, 23, 30, 33, 34, and 36. None of these are obvious in view of the cited references. For example, claims 1, 2, 30, 33, 34, and 36 are directed, in part, to pharmaceutical compositions and dosage forms (*e.g.*, tablets) of an optically pure enantiomer of fluoxetine. Morever, the pharmaceutical composition of claim 1 and the tablets of claims 33 and 34 are free or substantially free of lactose.

As admitted in the Office Action, El-Rashidy does not disclose compositions or dosage forms that comprise an optically pure enantiomer of fluoxetine.[1] El-Rashidy only alleges the preparation of tablets of racemic fluoxetine, and fails to suggest that pharmaceutical compositions or dosage forms containing an optically pure enantiomer of the drug are desirable. *See, e.g.*, col. 2, lines 52-55. This defect is not cured by the PDR.

The PDR reports that fluoxetine is a racemic mixture of R and S enantiomers, which have "essentially equivalent pharmacological activity." PDR at 919. But the PDR is directed to a pharmaceutical composition of the racemic compound, and does not suggest the preparation of compositions that are substantially free of one enantiomer of fluoxetine. Indeed, by stating that the pharmacological activities of the two enantiomers are "essentially equivalent," the PDR provides a *disincentive* to prepare compositions that contain an optically pure enantiomer of fluoxetine, since it is well known that the separation and purification of enantiomers can be expensive and time-consuming.

In short, the combination of El-Rashidy and the PDR suggests nothing more than that which is suggested by El-Rashidy alone; a tablet containing racemic fluoxetine. The

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[1] Compositions of the invention that comprise an "optically pure enantiomer" of a compound are substantially free of the opposite enantiomer of that compound. Specification at page 16, lines 9-19.

combination certainly does not suggest the pharmaceutical composition or tablets recited by claims 1, 33, and 34, which not only contain an optically pure enantiomer of fluoxetine, but are also free or substantially free of lactose. Indeed, neither El-Rashidy nor the PDR suggests the desirability of providing pharmaceutical compositions or dosage forms that are lactose-free.

Because there is no suggestion to select and combine various aspects of El-Rashidy and the PDR to provide even portions of the inventions recited by independent claims 1, 2, 30, 33, 34, and 36, Applicants respectfully submit that the rejection of these claims and their dependencies is based on the use of impermissible hindsight, and should therefore be withdrawn.

Applicants respectfully submit that the rejection of independent claims 13 and 14 and their dependencies should be withdrawn for similar reasons. As amended, these claims are directed, in part, to pharmaceutical compositions and dosage forms (*e.g.*, tablets) of optically pure fluoxetine that are free of lactose and that dissolve in more than three minutes when subjected to the dissolution test described in the specification (*i.e.*, the DISSOLUTION TEST).

As discussed above, neither El-Rashidy nor the PDR disclose or suggest tablets that comprise an optically pure enantiomer of fluoxetine. And while El-Rashidy alleges the measurement of commercially available tablets of *racemic* fluoxetine that dissolve in greater than three minutes, it provides no indication of whether or not those tablets are lactose free. Col. 5, lines 61-64. This is because El-Rashidy focuses on timed release tablets, not on tablets that are lactose free. This defect is neither cured by the PDR nor by the '629 application.

The '629 application is directed to the treatment of sleep disorders. An alleged disclosure on pages 3-4 of the reference is cited in the Office Action as evidence that "dissolution time is an art-recognized result-effective variable and it would have been obvious and well within the capability of the skilled artisan to optimize it [to achieve] the compositions of El-Rashidy." Office Action at page 5. Applicants are unable to identify the alleged disclosure on the cited pages of the '629 application.[2] However, even if the alleged

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[2] Pages 3 and 4 of the '629 application are cited in the Office Action in support of this allegation. However, those pages disclose only the structures of some compounds; they (continued...)

subject matter was disclosed in the reference, the '629 application would not render claims 13 and 14 obvious, even when combined with El-Rashidy and the PDR. This is because the "mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. at 2143.01 (emphasis in the original) (citing *In re Mills*, 916 F.3d 680 (Fed. Cir. 1990)).

None of the cited references suggest the desirability of the combination of each of the elements recited by claims 13 and 14. For example, nothing in any of the references suggest that it is desirable to provide tablets of optically pure fluoxetine that dissolve in greater than 3 minutes, much less lactose-free forms of such tablets. Indeed, El-Rashidy teaches away from such tablets by providing tablets that dissolve in only *15 seconds*. *See, e.g.*, El-Rashidy at col. 5, lines 60-61.

Because there is no suggestion to select and combine various aspects of El-Rashidy, the PDR, and the '629 application to provide even portions of the inventions recited by independent claims 13 and 14, the rejection of these claims and their dependencies is based on the use of impermissible hindsight. Applicants therefore respectfully request that their rejection be withdrawn.

Applicants also respectfully submit that the rejection of independent claims 21, 23, and 36, and their dependencies should be withdrawn. For example, claim 21 is directed, in part, to a compressed tablet that consists essentially of racemic fluoxetine, or an optically pure enantiomer or pharmaceutically acceptable salt thereof, microcrystalline cellulose, and pre-gelatinized starch. However, El-Rashidy alleges the preparation of a tablet that contains fluoxetine hydrochloride, calcium diphosphate dihydrate, a disintegrant, and a lubricant. *See, e.g.*, col. 2, lines 2-4. The reference discloses a laundry list of potential disintegrants, and singles out microcrystalline cellulose as the most preferred, but does not suggest a pharmaceutical composition or dosage form (*e.g.*, a compressed tablet) that contains racemic fluoxetine in combination with *two* disintegrants. Col. 3, lines 39-46. And El-Rashidy certainly does not suggest a compressed tablet that consists essentially of racemic fluoxetine or an optically pure enantiomer or salt thereof, and the particular combination of

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[2] (...continued)
disclose nothing about the dissolution times of particular tablets.

microcrystalline cellulose and pre-gelatinized starch. Because none of the other references cited in the Office Action disclose tablets that contain both microcrystalline cellulose and pre-gelatinized starch, their combination with El-Rashidy also does not suggest the tablet recited by claim 21. For this reason, Applicants respectfully request that the rejection of claim 21 and its dependencies be withdrawn.

Claims 23 and 36 are directed, in part, to anhydrous pharmaceutical compositions. In particular, claim 23 recites an anhydrous solid pharmaceutical composition which comprises racemic fluoxetine, an optically pure enantiomer of racemic fluoxetine or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable excipients. And claim 36 is directed, in part, to an anhydrous or non-hygroscopic pharmaceutical composition that contains an optically pure enantiomer of fluoxetine. None of the cited references disclose or suggest such pharmaceutical compositions.

For example, El-Rashidy takes no precautions to avoid the absorption of water during manufacturing, even though it is well known that many excipients readily absorb water, especially when dry. Indeed, El-Rashidy teaches away from the claimed invention by disclosing a preferred tablet that contains water in the form of dicalcium phosphate dihydrate. *See, e.g.*, col. 6, line 42. Similarly, neither the PDR nor the '629 application suggest the desirability of an anhydrous or non-hygroscopic tablet. Because none of the cited references teach or suggest an anhydrous or non-hygroscopic tablet, Applicants respectfully submit that the rejection of claims 23 and 36 is based on the use of impermissible hindsight. For this reason, it is respectfully requested that the rejection of these claims and their dependencies be withdrawn.

On pages 6-7 of the Office Action, claims 1, 2, 13, 14, 21, 23, 24, 30, and 33-35 are rejected under 35 U.S.C. § 102(b) over El-Rashidy in view of European Patent Application EP 0 693 281 to Mendizabal ("Mendizabal"). Applicants respectfully traverse this rejection.

Mendizabal alleges the preparation of pharmaceutical compositions that contain *racemic* fluoxetine, which are allegedly suitable for manufacturing *dispersable* tablets (*i.e.*, tablets that disintegrate in water in less than three minutes at 19°C - 21°C). *See, e.g.*, Mendizabal at page 5, lines 40-43. And while lactose is not listed as an ingredient in some of the tablets alleged by Mendizabal, the reference explicitly teaches that lactose is an excipient suitable for use in the preparation of compressed tablets of fluoxetine. *See, e.g.*, page 3, line 55. In sum, Mendizabal provides no suggestion of pharmaceutical compositions or dosage

forms that contain an optically pure enantiomer of fluoxetine, no suggestion that lactose-free pharmaceutical compositions or dosage forms are desirable, and no suggestion that anhydrous or non-hygroscopic pharmaceutical compositions and dosage forms are desirable.

It is therefore clear that Mendizabal does not disclose or suggest any of the various pharmaceutical compositions and dosage forms recited by the pending claims. It simply discloses a number of excipients, including lactose, that can be combined with racemic fluoxetine. But even when combined with El-Rashidy, the PDR, and the '629 application, Mendizabal provides no guidance or suggestion that would have made the specific pharmaceutical compositions and dosage forms claimed in the present application obvious to one of ordinary skill in the art.

Because none of the claimed pharmaceutical compositions and dosage forms are obvious in view of any of the cited references, Applicants respectfully submit that the use of such pharmaceutical compositions and dosage forms would also not have been obvious. As pointed out in the Office Action, Mendizabal does disclose the use of racemic fluoxetine in the treatment of depression. But even when combined with the other references cited in the Office Action, Mendizabal does not suggest the method recited by claim 35. Applicants therefore respectfully request that the rejection of 1, 2, 13, 14, 21, 23, 24, 30, and 33-35 under 35 U.S.C. § 102(b) be withdrawn.

CONCLUSION

Applicants believe that all pending claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner deem it helpful, a personal or telephone interview is respectfully requested to discuss any remaining issues in an effort to expeditiously advance the application to allowance.

No fee is believed to be due for this submission. Please charge the required fees to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date: April 19, 2001

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Enclosures

APPENDIX A

Amendments

IN THE CLAIMS

13. (Twice Amended) A chemically stable compressed tablet free of lactose which comprises [racemic fluoxetine,] an optically pure enantiomer of fluoxetine or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient, wherein said tablet does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

14. (Twice Amended) A chemically stable compressed tablet free of lactose which comprises about 1% to about 50% by weight of [racemic fluoxetine,] an optically pure enantiomer or a pharmaceutically acceptable salt thereof, and about 99% to about 50% by weight of at least one pharmaceutically acceptable excipient, wherein said tablet does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

17. (Amended) The [composition] compressed tablet of claim 13 or 14, wherein said fluoxetine is present in an amount from about 1 mg to about 200 mg.

18. (Amended) The [composition] compressed tablet of claim 17, wherein said fluoxetine is present in an amount of about 2 mg to about 100 mg.

19. (Amended) The [composition] compressed tablet of claim 13 or 14, wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

20. (Amended) The [composition] compressed tablet of claim 13 or 14, wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.

22. (Amended) The [solid pharmaceutical composition] compressed tablet of claim 13 or 14, wherein said compressed tablet is sterile, anhydrous and non-hygroscopic.

29. (Amended) The composition or tablet of claim 1, 13, 14, 21, 23, or 24 wherein said pharmaceutically acceptable salt is a hydrochloride salt.

30. (Twice Amended) A stable pharmaceutical unit dosage form which comprises [racemic fluoxetine,] an optically pure enantiomer of [racemic] fluoxetine, or a pharmaceutically acceptable salt thereof, and one of more pharmaceutically acceptable excipients wherein said dosage form is not a capsule or gel cap and does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

35. (Amended) A method of treating depression in a mammal which comprises the oral administration of a therapeutically effective amount of a composition or tablet of [claims] claim 1, 2, 13, 14, 21, 23, 24, 30, 33 or 34 to said mammal.

38. (canceled without prejudice)

APPENDIX B

Pending Claims

1. A lactose-free pharmaceutical composition which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof, and at least one non-lactose pharmaceutically acceptable excipient.

2. A solid pharmaceutical composition which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable excipient, wherein said excipient is not lactose.

3. The composition of claim 1, wherein said non-lactose pharmaceutically acceptable excipient is a binder, a filler, or a mixture thereof.

4. The composition of claim 2, wherein said pharmaceutically acceptable excipient is a binder, a filler, or a mixture thereof.

5. The composition of claim 3 or 4 wherein said binder is a starch.

6. The composition of claim 3 or 4 wherein said binder is a cellulose.

7. The composition of claim 5 wherein said starch is selected from the group consisting of corn starch, potato starch, pre-gelatinized starch and a mixture thereof.

8. The composition of claim 6 wherein said cellulose is selected from the group consisting of ethyl cellulose, cellulose acetate, carboxymethyl cellulose calcium, sodium carboxymethyl cellulose, methyl cellulose, hydroxypropyl methyl cellulose, microcrystalline cellulose and a mixture thereof.

9. The composition of claim 3 or 4, which further comprises a lubricant, disintegrant, or mixtures thereof.

10. The composition of claim 1 or 2, wherein said enantiomer of fluoxetine is (R)-fluoxetine.

11. The composition of claim 1 or 2, wherein said enantiomer of fluoxetine is (S)-fluoxetine.

12. The composition of claim 1 or 2, wherein said pharmaceutical composition is substantially free of all mono- or di-saccharides.

13. A chemically stable compressed tablet free of lactose which comprises an optically pure enantiomer of fluoxetine or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient, wherein said tablet does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

14. A chemically stable compressed tablet free of lactose which comprises about 1% to about 50% by weight of an optically pure enantiomer or a pharmaceutically acceptable salt thereof, and about 99% to about 50% by weight of at least one pharmaceutically acceptable excipient, wherein said tablet does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

15. The compressed tablet of claims 13 or 14 wherein said tablet does not contain a disintegrant.

16. The compressed tablet of claim 13 or 14 wherein said tablet dissolves and disperse uniformly in more than five minutes when subjected to the DISSOLUTION TEST.

17. The compressed tablet of claim 13 or 14, wherein said fluoxetine is present in an amount from about 1 mg to about 200 mg.

18. The compressed tablet of claim 17, wherein said fluoxetine is present in an amount of about 2 mg to about 100 mg.

19. The compressed tablet of claim 13 or 14, wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

20. The compressed tablet of claim 13 or 14, wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.

21. A stable, solid compressed tablet consisting essentially of racemic fluoxetine, an optically pure enantiomer or a pharmaceutically acceptable salt thereof, and microcrystalline cellulose and pre-gelatinized starch.

22. The compressed tablet of claim 13 or 14, wherein said compressed tablet is sterile, anhydrous and non-hygroscopic.

23. An anhydrous solid pharmaceutical composition which comprises racemic fluoxetine, an optically pure enantiomer of racemic fluoxetine or a pharmaceutically acceptable salt thereof, and one or more pharmaceutically acceptable excipients.

24. The composition of claim 23 wherein said composition does not contain lactose.

25. The composition of claim 23 or 24 wherein said composition is a compressed tablet.

26. The composition of claim 23 or 24 wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

27. The composition of claim 23 or 24 wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.

28. The composition of claim 23 or 24 wherein said composition is non-hygroscopic.

29. The composition or tablet of claim 1, 13, 14, 21, 23, or 24 wherein said pharmaceutically acceptable salt is a hydrochloride salt.

30. A stable pharmaceutical unit dosage form which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof, and one of more pharmaceutically acceptable excipients wherein said dosage form is not a capsule or gel cap and does not dissolve in less than three minutes when subjected to the DISSOLUTION TEST.

31. The unit dosage form of claim 30 wherein said fluoxetine enantiomer is optically pure (R)-fluoxetine.

32. The unit dosage form of claim 30 wherein said fluoxetine enantiomer is optically pure (S)-fluoxetine.

33. A solid compressed tablet substantially free of lactose which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient which is not lactose.

34. A disintegrating tablet substantially free of lactose which comprises an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof, and at least one pharmaceutically acceptable excipient which is not lactose.

35. A method of treating depression in a mammal which comprises the oral administration of a therapeutically effective amount of a composition or tablet of claim 1, 2, 13, 14, 21, 23, 24, 30, 33 or 34 to said mammal.

36. An anhydrous or non-hygroscopic pharmaceutical composition consisting essentially of an optically pure enantiomer of fluoxetine, or a pharmaceutically acceptable salt thereof; and at least one pharmaceutically acceptable excipient, wherein the composition is substantially free of unbound water.

37. The compressed tablet of claim 21 wherein said tablet dissolves in more than five minutes when subjected to the DISSOLUTION TEST.